The claim rejections under 35 U.S.C. 112 stated in paragraphs 5 and 6 of the Detailed Action are believed to have been overcome by the amendments made herein to independent claims 1and 2. The state of the heated blank has been defined as being dough-like or honey-like. This is based on the equivalent statements found on page 17, lines 10 - 12 of the Specification.

Before proceeding to the remaining claim rejections, it is desired to point out the following.

The present invention is predicated on treating a blank of fiber reinforced material consecutively in different portions of an apparatus.

Specifically, as shown in Figs. 4 and 5 of the present application, and described in detail in the related portions of the Specification, the blank is placed in a heating stage 10 (Fig. 4). After being heated to the point where it has a dough-like or honey-like consistency, an extrusion die 7 is used to force that softened blank into the negative mold 11 which is caused to be filled completely with that material, thereby conforming it to the shape of the negative mold and producing the desired end effect.

It is respectfully submitted that the references do <u>not disclose</u> that concept.

Consider, for example, European Patent EP 0 373 294 which has been relied upon to reject most of the claims under 35 USC 102 and which can perhaps be properly considered as the principal reference.

In none of the many embodiments of that reference does there take place a heating of the blank in one portion of a mold arrangement, followed by transfer to a shape-forming portion of that arrangement.

The Office Action specifically refers to Fig. 6 of that European patent. As explained therein, especially in columns 8 and 9, the blank 6 is placed into a mold 20 in which it is heated to soften but not to melt. While still in that same mold 20, there is axially inserted into that mold a "pressure stick 40". The force exerted by that pressure stick 40 spreads apart the blank 6 within mold 20 and causes its outer surface to conform to mold 20. During all this, the blank 6 never moves from its initial location in mold 20.

The same technique is used in every other embodiment of the European patent reference. In none of them is there the slightest indication that the blank should be transferred from one mold segment to another, as is required by independent claims 1 and 2, and by reference, in each and every other claim of the present application.

Therefore, the rejection (paragraph 8 of the Office Action) of claims 1 - 4, 7, 11 and 14 under 35 USC 102 over the European reference is believed to be unwarranted.

The rejection (paragraph 9 of the Office Action) of claims 1 - 5, 7, 11, 12 and 14 is also believed to be unwarranted.

This rejection is in the alternative: either under 35 USC 102 over the Japanese reference JP 02-145-327, alone, or under 35 USC 103 over a proposed combination with the European patent reference.

What has been said previously about the European patent also applies to the Japanese reference. It also does not disclose the transfer feature of applicant's invention and therefore the rejection under Section 102 is believed to be unwarranted.

As for the proposed combination, since neither reference discloses, or even suggests the transfer feature, their combination also does not make this obvious.

Claims 5, 6, 12 and 15 have been rejected (paragraph 13 of the Office Action) under 35 USC 103 over a proposed combination of the European patent reference and the GAPP reference.

This rejection is believed to be unwarranted. As previously pointed out, applicant submits that the European patent reference does not teach the basic claimed process as defined in independent claims 1 and 2. Therefore, the rejection of dependent claims 5, 6, 12 and 15 is also believed to be unwarranted, inasmuch as GAPP also does not supply the features missing from the European patent reference.

Claims 6, 8 and 15 have been rejected (paragraph 14 of the Office Action) under 35 USC 103 over a proposed three-way combination of the Japanese reference, the European patent reference, and the GAPP reference.

It has been previously pointed out that the Japanese reference, even if combined with the European patent reference, would not disclose the basic features of independent claims 1 or 2.

Accordingly, dependent claims 6, 8 and 15 are also not subject to such rejection since GAPP likewise fails to supply the missing features.

Claims 8 and 10 have been rejected (paragraph 15 of the Office Action) under 35 USC 103 over a proposed three-way combination of the Japanese reference with the European patent reference and in further combination with the Gotoh et al. reference.

Gotoh has apparently been cited only for specific molding temperatures, but this does not detract from the distinguishing features previously pointed out of independent claims 1 or 2 and therefore also does not warrant rejection of dependent claims 8 and 10.

Claims 8 and 10 have been further rejected (paragraph 16 of the Office Action) under 35 USC 103 over a proposed combination of the European patent reference with the same Gotoh patent discussed above.

It is submitted that for the same reasons advanced above, this rejection is unwarranted.

Claim 16 has been rejected (paragraph 17 of the Office Action) over a proposed combination of the European patent reference with the German reference DE 3739582.

This rejection is believed to be unwarranted because claim 16 depends on claim 1 previously discussed and claim 1 distinguishes from the principal reference by features which are not supplied by the German reference.

Claim 16 has been further rejected (paragraph 18 of the Office Action) under 35 USC 103 over a proposed combination of the Japanese reference, the European patent reference and the German reference.

This rejection is believed to be unwarranted for the reasons stated before with respect to claim 16, because the secondary references do not disclose, or suggest the features missing from the Japanese reference.

Finally, claims 9 and 13 have been rejected (paragraph 19 of the Office Action) under 35 USC 103 over either the European patent reference alone or a proposed combination of the Japanese reference with the European patent reference.

This rejection is believed to be unwarranted for the same reasons as previously stated with respect to the rejection of claim 16.

In view of the foregoing, it is submitted that the rejections of claims are unwarranted, the application is in condition for allowance, and corresponding action is hereby solicited.

Respectfully submitted,

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Application No.: 08/849,746
Examiner: S. Staicovici

37 CFR §1.121(b)(1)(iii) and (c)(1)(ii) SPECIFICATION AND CLAIM AMENDMENTS- MARKED UP VERSION

AMENDED ABSTRACT (Marked-up version)

-- An [extended] extruded component made of fibre-reinforced thermoplastic materials, in particular a screw (1) that contains a corresponding proportion of fibres. Carbon fibres [haped] shaped as [endles] endless fibres extend in an at least approximately parallel direction to the centre line of the screw (1) in the area of the head (2) of the adjacent thread turns of the shaft (5). At the surface of the remaining part of the threaded portion, the [fibre] fibres follow the contour of the thread in the axial direction of the part. The fibres in the core of this section next to the end of the screw are [distrubuted] distributed in an increasingly random manner towards the free end of the screw.

AMENDED SPECIFICATION (Marked-up version)

On page 10, delete the paragraph which starts with the expression "Fig. 7" and continues to line 26 on page 11, and substitute therefor the following:

-- Fig. 7 a top view of a component manufactured using the push-pull extrusion process, which can be specifically used as an osteosynthesis plate.

DETAILED DESCRIPTION OF THE INVENTION

In the following explanation of the process according to the invention, as well as of the components manufactured according to the process, it is assumed that the component (in accordance with Figures 1 to 5) is a connection element, particularly a screw, which is specifically used in medical technology, in other words as a corticalis screw or spongiosa screw, for example, or that the component (in accordance with Figures 6 and 7) is a mounting part, particularly an osteosynthesis plate for interacting together with a connection element as mentioned above.

Within the scope of the invention, of course, other components are also included, if they consist of fiber-reinforced thermoplastic materials and are manufactured in a process according to the invention. The use of such components is not limited only to medical technology. It is certainly possible to use such components also in other areas of application, such as in machine construction, in electrical technology, in aerospace technology, in civil engineering, etc. The components do not always necessarily have to be manufactured in the form of connection elements (screws), but can also be used as components with completely different design forms, such as rails or plates, for example. It would be possible, for example, to equip the components made of fiber-reinforced thermoplastic materials, which are probably not structured as self-tapping screws, with a corresponding drill section, which can also be made from biocompatible material, if necessary, or can easily be removed after the drilling process. Under some circumstances, such removal would not even be necessary in various areas of application. The example is also explained on the basis of a fiber-

reinforced thermoplastic material which is produced with endless fibers with a volume proportion of more than 50%. Using the process according to the invention, however, it is just as advantageous to process fiber-reinforced thermoplastic materials which contain only short fibers or long fibers or combinations of proportions of short, long, and/or endless fibers. The process according to the invention can also be successfully used with a fiber proportion of less than 50 volume-% in the blank. --

On page 11, delete the paragraph which starts on line 27 with "The connection element" and continues to line 16 on page 12 and substitute therefor the following:

-- The connection element shown in the drawing, in the form of a screw 1, essentially consists of a head 2, an engagement part 3 for force introduction by a turning tool, and a shaft 5 provided with a thread 4. As is particularly evident from Fig. 2 of the drawing, the main point of the screw 1 [2[sic]] is the progression of the endless fibers 6. By means of fibers aligned in locally targeted manner with the structure, the screw 1 [2[sic]] has different degrees of rigidity, adjusted in locally targeted manner. This makes it possible to adapt the rigidity to the natural structure of a bone, particularly when the screw is used as a corticalis screw. By selection of a laminate of thermoplastic materials with carbon fibers, a light, x-ray-transparent, and biocompatible connection element can be created. The particular advantage of such a screw lies in the fact that the rigidity and the rigidity gradients can be better adapted to the natural structure of the bone than in the case of conventional metal screws. By means of the fiber structure, a better force distribution is guaranteed, i.e. not

only the first three screw turns are the bearing parts. Furthermore, the connection element does not hinder conventional medical examination methods, since it is non-magnetic and x-ray-transparent. This is a particular disadvantage of conventional metal implants, including connection elements. They can make the examination findings of modern diagnostic methods, such as computed tomography and magnetic resonance imaging, totally useless. --

On page 14, delete the paragraph which starts with the words "In research work" on line 1 and substitute therefor the following:

-- In research work in this field, it was found that only when using bone screws made of thermoplastic materials reinforced with carbon fibers and, in this connection, by means of the manufacturing process according to the invention, was it possible to create an optimum variant. Based on the extrusion process developed in this connection, bone screws made of PAEK [PEAK] reinforced with carbon fibers were manufactured and characterized.

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CLAIM AMENDMENTS (Marked-up version)

1. **THREE TIMES AMENDED** A process for manufacturing components made of fiber-reinforced thermoplastic materials, where a blank formed of fibers and a thermoplastic materials is first pre-finished, and said blank is brought into a final form of a component is a negative mold, under pressure, in a hot-forming process, comprising the steps of:

heating the entire blank to a forming temperature with dough-like, or honey-like consistency in a heating stage,

pressing said heated blank into the negative mold and,

shaping the blank in the negative mold by virtue of the entire blank flowing from the heating stage into the negative mold.

2. **THREE TIMES AMENDED** A process for manufacturing components which are under stress, made of fiber-reinforced thermoplastic materials, where a blank formed with a fiber proportion of more than 50 volume-% and with at least predominant use of endless fibers and said fiber-reinforced thermoplastic material is first pre-finished, and said blank is brought into a final form of a component in a negative mold, under pressure, in a hot-forming process, comprising the steps of:

heating the entire blank to a forming temperature with dough-like, or honey-like consistency in a heating stage,

pressing said heated blank into the negative mold and,

shaping the blank in the negative mold by virtue of the entire blank flowing from the heating stage into the negative mold.